



Attorney Docket No. 55046 (70207)

1624  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**APPLICANT(S):** Walsh, et al

**SERIAL NO:** 10/017,324

**EXAMINER:** 1624

TECH CENTER 1600 2900

**FILED:** December 15, 2001

**GROUP ART NO:** Unassigned

**FOR:** **METHODS FOR PREPARATION OF MACROCYCLIC MOLECULES AND  
MACROCYCLIC MOLECULES PREPARED THERAPY**

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on July 25, 2002.

By: Maggie C. Hamelin  
Maggie C. Hamelin

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Date: July 25, 2002

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II. COPIES

- a. ☒ Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

- a. ☐ Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report, a copy of which is attached hereto (concise explanation not required).
- b. ☐ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. ☐ The following additional information is provided for the Examiner's consideration:

**FEES**

IV. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)

(check one box)

- a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1)). No fee or certification is required.
- b. ☐ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b) (2)). No fee or certification is required.
- c. ☐ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below, or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):

(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c) (2)).

- a. ☐ No certification; therefore, a fee in the amount of \_\_\_\_\_ is required by 37 C.F.R. § 1.17(p).  
or
- b. ☐ See the certification below. No fee is required.

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby certifies that

- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making

reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

c. ☐

Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.



Please charge Deposit Account No. 04-1105 in the amount of \$ \_\_\_\_\_ for the above-indicated fee. A triplicate copy of this paper is attached.



No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition, if necessary) and charge the appropriate fee to Deposit Account No. 04-1105.

Respectfully submitted,



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Date: July 25, 2002



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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT



DOCKET NO:

55046 (70207)

SERIAL NO.:

10/017,324

TECH CENTER 1600-2900

APPLICANT(S): Walsh, et al.

FILING DATE:

December 15, 2001

GROUP NO. : 1645

## UNITED STATES PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA	5,883,293	03/1999	Gilon et al.			
AB	5,847,121	12/1998	Yau et al.			

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO
BA 00/36093	06/2000	PCT			

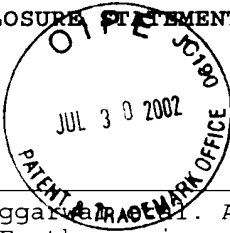
## OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

CA	Y.Xue et al. Nature, vol 403 (2000) 571-575, "Alternative modular polyketide synthase expression controls macrolactone structure."
CB	L.Tang et al. Chem. & Biol. vol 7 No.2 (2000) 77-84, "Formation of functional heterologous complexes using subunits from the picromycin, erythromycin and oleandomycin polyketide synthases."
CC	R.McDaniel et al. Proc. Natl. Acad. Sci. USA vol 96 (1999) 1846-1857, "Multiple genetic modifications of the erythromycin polyketide synthase to produce a library of novel 'unnatural' natural products."
CD	R. Gokhale et al. Chem. & Biol., "Mechanism and specificity of the terminal thioesterase domain from the erythromycin polyketide synthase."
CE	C. Kao et al. J. Am. Chem. Soc. 119 (1997) pp. 1139-1140, "Gain of Function Mutagenesis of the Erythromycin Polyketide Synthase. 2. Engineered Biosynthesis of an Eight-Membered Ring Tetraketide Lactone"
CF	J.Jacobsen et al. Science vol 277 (1997) 367-369 "Precursor-Directed Biosynthesis of Erythromycin Analogs by an Engineered Polyketide Synthase"
CG	J.Humphrey et al. Am. Chem. Soc. 97 (1997) pp 2243-2266, "Chemical Synthesis of Natural Product Peptides: Coupling Methods for the Incorporation of Noncoded Amino Acids into Peptides."
CH	T. Stachelhaus et al. Science vol 269 (1995) pp 69-72, "Rational Design of Peptide Antibiotics by Targeted Replacement of Bacterial and Fungal Domain"
CI	J.Cortes et al. Science vol 268 (1995) pp 1487-1489, "Repositioning of a Domain a Modular Polyketide Synthase to Promote Specific Chain Cleavage"

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FORM PTO-1449		DOCKET NO: 55046 (70207)	SERIAL NO.: 10/017,324
INFORMATION DISCLOSURE STATEMENT 		APPLICANT(S): Walsh, et al.	
		FILING DATE: December 15, 2001	GROUP NO.: 1645
CJ	R. Aggarwal, J. Am. Chem. Soc. vol 15 (1995) pp 1517-1520. "The Thioesterase of the Erythromycin-producing Polyketide Synthase: Mechanistic Studies in vitro to Investigate its Mode of Action and Substrate Specificity:		
EXAMINER:		DATE:	

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